K013862

FEB 21 2002

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Summary of Safety and Effectiveness

Submitter:	BCI, Inc.
Address:	N7 W22025 Johnson Road Waukesha, WI 53186
Telephone:	(262) 542-3100
Contact:	VP Regulatory Affairs
Prepared:	November 15, 2001
Proprietary Name:	BCI® 1621 Oximetry Data Management Program
Common/Classification Name:	Pulse Oximeter Display Software
Predicate Devices:	BCI® 3403 Sleep Screening Pulse Oximeter (K011156) Nellcor Score™ Software (K961450)

New Device Description:

The BCI® 1621 Oximetry Data Management Program is a software program used as a pulse oximetry accessory.

Intended Use:

The BCI® 1621 Oximetry Data Management Program provides a printed oximetry data analysis report and graphical SpO_2 trend. It is designed for health care professionals in environments such as hospitals, skilled nursing facilities, physician offices, and home care. It can aid in the analysis of pulse oximetry data from sleep screening, oxygen therapy validation, and/or related studies. A unique cable is used to download data from the BCI 3403 pulse oximeter or compatible device.

Performance Data:

The design of this device utilizes currently available technology found in legally marketed devices. The software performs the same analysis as the BCI 3403 pulse oximeter (K011156). In addition, it performs desaturation analysis, constructs histograms, and SpO_2 graphs similar to the Nellcor Score™ software (K961450).

Software development and testing was conducted in accordance with the *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices,* FDA, May 29, 1998. Testing of device performance included clinical testing of the desaturation identification algorithm and overall software validation using simulators. The results demonstrated that the BCI® 1621 Oximetry Data Management Program performed within its specifications.

Based on these results, it is our determination that the device is safe, effective, and performs as well as the legally marketed predicate device(s).

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Respectfully,

Donald Alexander
VP Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2002

Mr. Donald J. Alexander
BCI, Inc.
N7 W22025 Johnson Road
Waukesha, WI 53186-1856

Re: K013862
BCI 1621 Oximetry Data Management Program
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: February 8, 2002
Received: February 11, 2002

Dear Mr. Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

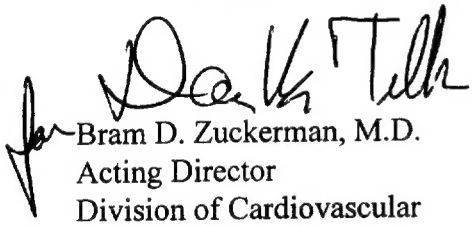
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if Known): K013862

Device Name: BCI 1621 Oximetry Data Management Program

Indications For Use:

Intended Use:

The BCI 1621 Oximetry Data Management Program analyzes data recorded using the BCI 3403 pulse oximeter and provides a printed oximetry data analysis report and graphical SpO_2 trend. This information can aid in the analysis of pulse oximetry data. Data from the BCI 3403 pulse oximeter are downloaded for analysis using a unique cable.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013862

Prescription Use X OR Over-The_Counter Use _____
(Per 21 CFR 801.109)